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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 10/567,372  | 04/13/2007  | Jozef Frans Nelissen | 5100-0000032/US           | 9863             |
| 30593   | 7590        | 10/16/2008           | EXAMINER                  |                  |
| HARNESS, DICKEY & PIERCE, P.L.C.<br>P.O. BOX 8910<br>RESTON, VA 20195 |             |                      | HAWTHORNE, OPHELIA ALTHEA |                  |
|   |             | ART UNIT             |                           | PAPER NUMBER     |
|   |             | 3772                 |                           |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                       |  |
|------------------------------|------------------------|-----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>   |  |
|                              | 10/567,372             | NELISSEN, JOZEF FRANS |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>       |  |
|                              | OPHELIA HAWTHORNE      | 3772                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 April 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 - 25 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) 1 - 25 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 07 February 2006 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07 February 2006</u> .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed on 02-07-06.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. **Claims 13 – 14, 17 & 21 – 25** rejected under 35 U.S.C. 103(a) as being unpatentable over **Halstrom (US 5,868,138)** in view of **Toone (US 4,901,737)**.

**Regarding claim 13,** Halstom substantially discloses a device (**20, Fig. 1**) for treating breathing problems (**[Col. 2] lines 44 – 46**), comprising a shaped part (**32**)

fitting onto the teeth of the lower jaw, a shaped part (28) fitting onto the teeth of the upper jaw, and at least one adjustable connecting means (40) between the upper (28) and lower (32) shaped part for forward/backward (**apertures 68, Fig. 7**) and upward/downward adjustment (**stylus 46, Fig. 7**) & ([Col. 6], lines 17 – 19) of the upper shaped part (28) relative to the lower shaped part (28), one of the shaped parts (32) is provided at the front with a slide mechanism (48) including a slide element (48) which is slidable laterally to a limited extent along a guide element (50), the adjustable connecting means (40) are fixedly connected to the other shaped part (32) on one side and to the slide element on the other (**as shown in Fig. 7**).

Halstrom substantially described the invention as claimed, except for the adjustable connection means comprising a horizontal adjusting screw for forward/backward adjustment of the one shaped part relative to the other, the screw being connected by means of a connecting piece with the adjustable connection means for the upward/downward adjustment. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx ([Col. 1], lines 11 – 14). The device (9a) comprising an horizontal screw or a threaded adjustment rod (50) & ([Col. 10], lines 65 – 66) capable of forward/backward adjustment of one of the shaped part (14) relative to the other, the screw or threaded adjustment rod (50) being connected by means of a connecting piece

in the form of a threaded bore (52) for the upward/downward adjustment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting means of Halstrom to have a horizontal screw for forward/backward adjustment of the one shaped part relative to the other, the screw being connected by means of a connecting piece with the adjustable connection means for the upward/downward adjustment taught by Toone since doing so would reduce sleep apnea due to intermittent closures or partial obstruction in the oropharynx.

**Regarding claim 14**, Halstrom discloses the dimensions of the guide element (50) and the slide element (48) are closely-sized transversely of the guiding direction (as shown in Fig. 7).

**Regarding claim 17**, Halstrom discloses the slide element (48) can be snapped onto the guide element (50) via the cavity (54).

**Regarding claim 18**, Halstrom discloses the adjustable connecting means (40) comprising a substantially vertical adjusting screw (**stylus 46**) with double screw thread for upward/downward adjustment ([Col. 6], lines 17 – 19) of the upper shaped part (28) relative to the lower shaped part (32), which adjusting screw co-acts on one outer end with a first threaded bore (52) connected via a connecting piece to the slide element (48) and which co-acts on its other outer end with a second threaded bore (68) provided on the front side of the other shaped part (28), wherein a rotation of the adjusting screw (46) changes the distance between the lower and upper threaded bores ([Col. 7], lines 29 – 32).

**Regarding claim 21**, Halstrom discloses the adjustable connecting means (**40**) comprising a substantially vertical adjusting screw (**46**) and threaded bore (**68**) co-acting therewith for the upward/downward adjustment (**[Col. 6], lines 17 – 19**) of the upper shaped part (**28**) relative to the lower shaped part (**32**).

**Regarding claim 22**, Halstrom substantially described the invention as claimed, see rejection to claim 13 above; except the horizontal adjusting screw for forward/backward adjustment of the one shaped part relative to the other co-acts on one outer end with a threaded passage. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx (**[Col. 1], lines 11 – 14**). The device (**9a**) comprising an horizontal screw or a threaded adjustment rod (**50**) & (**[Col. 10], lines 65 – 66**) capable of forward/backward adjustment of one of the shaped part (**14**) relative to the other co-acts on one outer end with a threaded passage or a threaded bore (**52**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting means of Halstrom to have a horizontal screw for forward/backward adjustment of the one shaped part relative to the other co-acts on one outer end with a threaded passage taught by Toone since doing so would reduce sleep apnea due to intermittent closures or partial obstruction in the oropharynx.

**Regarding claim 23**, Halstrom substantially described the invention as claimed, see rejection to claim 22; except for the threaded passage is provided in the slide element and the horizontal adjusting screw is provided on its other outer end with a screw head, the connecting piece being provided with a horizontally oriented hole through which the horizontal adjusting screw extends. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx (**[Col. 1], lines 11 – 14**). The device (**9a**) comprising a threaded passage (**52**) is provided in the slide element (**53**) and the horizontal screw (**50**) is provided on its outer end with a screw head (every screw has a head portion), the connecting piece being provided with a horizontal oriented hole (**52**) through which the horizontal adjusting screw extends. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting means of Halstrom to have the threaded passage is provided in the slide element and the horizontal adjusting screw is provided on its other outer end with a screw head, the connecting piece being provided with a horizontally oriented hole through which the horizontal adjusting screw extends taught by Toone since doing so would provide a means for reducing sleep apnea due to intermittent closures or partial obstruction in the oropharynx.

**Regarding claim 24,** Halstrom substantially described the invention as claimed, see rejection to claim 22; except the threaded passage is provided in the connecting piece, and the slide element is provided with a horizontally oriented hole through which the horizontal adjusting screw extends. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx (**[Col. 1], lines 11 – 14**). The device (**9a**) comprising a threaded passage (**52**) is provided in the connecting piece (**Fig. 9a**) and the slide element (**54**) is provided with a horizontally oriented hole through which the horizontal adjusting screw (**50**) extends. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting assembly of Halstrom to have threaded passage is provided in the connecting piece, and the slide element is provided with a horizontally oriented hole through which the horizontal adjusting screw extends taught by Toone since doing so would provide a means for reducing sleep apnea due to intermittent closures or partial obstruction in the oropharynx.

**Regarding claim 25,** Halstrom discloses the adjustable connection means (**40**) for the upward/downward adjustment are partially built in a shaped part (**as shown in Fig. 7**).

5. **Claims 15 – 16 & 19 - 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Halstrom (US 5,868,138)** in view of **Toone (US 4,901,737)** and further in view of **Lowe (US 5,409,017)**.

**Regarding claim 15**, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 13 above; except for the guide element is a rod mounted between two points of the one shaped part, and the slide element is a hollow tube slidable around this rod. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Lowe teaches a mandible repositioning appliance (**Fig. 2**) for treatment of snoring and sleep apnea (**[Col. 1], lines 44 - 46**). The device having a guide element which is a rod (**54, 56, Fig. 3**) mounted between two points of one of the shaped part, and the slide element is a hollow tube (**58, 60**) slidable around the rod (**[Col. 3], lines 30 – 36**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guide and slide elements of Halstrom and Toone wherein the guide element is a rod and the slide element is a hollow tube taught by Lowe since doing so would serve to maintain the axial alignment of the upper and lower shaped part and prevent relative rotation of the anterior and posterior sections.

**Regarding claim 16**, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 13 above; except the length of the hollow tube is chosen as a function of the desired maximum lateral displacement. In addition,

Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Lowe teaches a mandible repositioning appliance (**Fig. 2**) for treatment of snoring and sleep apnea (**[Col. 1], lines 44 - 46**). The device comprising hollow tubes or parallel guide passage (**58, 60**) capable of functioning at the desired maximum lateral displacement. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Halstrom and Toone comprising a slide element wherein the length of the hollow tube is chosen as a function of the desired maximum lateral displacement taught by Lowe in order to maintain the axial alignment of the upper and lower shaped part.

**Regarding claim 19**, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 18 above; except for the adjusting screw is provided substantially in the middle with an encircling flange with radially directed openings in which a rod fits for the purpose of turning the adjusting screw through rotation of the rod. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Lowe teaches a mandible repositioning appliance (**Fig. 2**) for treatment of snoring and sleep apnea (**[Col. 1], lines 44 - 46**). The device comprising an adjusting screw or threaded nut (**68**) provided substantially in the middle (**as shown in Fig. 3**) encircling a flange (**76**) with radially directed openings (**78**) in which a rod (**82**) & (**[Col. 3], lines 60 – 61**) fits for the purpose of turning the adjusting a screw through

rotation of the rod. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the adjusting screw of Halstrom and Toone to have a flange with directed openings in which a rod fits taught by Lowe in order to rotate the adjusting member and thus adjust the axial relative positions of both the upper and lower shaped parts.

**Regarding claim 20**, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 18 above; except for the vertical adjusting screw is enclosed on both sides by telescopically acting tubes. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof (**[Col. 8], lines 50 – 52**).

However, Lowe teaches a mandible repositioning appliance (**Fig. 2**) for treatment of snoring and sleep apnea (**[Col. 1], lines 44 - 46**). The device comprising a vertical adjusting screw (**70**) enclosed on both sides by telescoping acting tube (**74**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Halstrom and Toone to have telescoping acting tubes by which a vertical adjusting screw can be enclosed taught by Lowe in order to limit lateral movement of the upper and lower shaped part.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is

(571)270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ophelia Hawthorne/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772